# The impact of market forces on the sustainability of the biotechnology industry

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**Abstract:** This paper contains a warning for investors, executives, analysts and scientists about the sustainability of the biotechnology industry. The study upon which the paper is based examines the impact of market forces on the biotechnology industry and argues that the short-term focus of market driven policies and practices impacts on the sustainability of firms operating in the industry. The market is represented by the National Association of Securities Dealers, Automated Quotations Market (NASDAQ), considered to be one of the vehicles of the promotion of 'new economy' companies and principles. Through the application of bibliometric data (using both refereed and non-refereed papers), matched with the long term tracking of the NASDAQ Biotechnology Index, the authors provide a clear indication that the short-term investment thinking is leading an industry that is characterised by long R&D cycles. There is an incompatibility between the shorter-term investment considerations and the long-term scientific developments the biotechnology industry is attempting to achieve. Graphs and illustrations are provided to portray the comparative data.

**Keywords:** Biotechnology; ICT; fads; sustainability.

**Reference** to this paper should be made as follows: Hine, D. and Griffiths, A. (2004) 'The impact of market forces on the sustainability of the biotechnology industry', *Int. J. Entrepreneurship and Innovation Management*, Vol. 4, Nos. 2/3, pp.138–149.

**Biographical notes:** Damian's major research interests revolve around entrepreneurship and innovation, particularly in the Biotechnology industry. He has numerous international publications in small business and entrepreneurship and is currently completing a book on BioEntrepreneurship and Innovation for Edward Elgar Publishers. Damian also works closely with companies and organisations in the Biotechnology industry in terms of advising, mentoring and supporting start-up ventures which largely emanate from scientific research projects with commercialisable IP. Damian has also recently completed an international aid project on Technology Transfer of publicly funded research in the Philippines.

Dr. Andrew Griffiths has recently joined the UQ Business School. Andrew's areas of research include: the management of corporate change and innovation, strategic issues relating to the pursuit of corporate sustainability and the development of human capital and e-commerce and innovation. He has published three books on corporate sustainability. He has published in international journals, including The Academy of Management Review and the Journal of Management Studies. He has worked with a range of organisations

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## 1 Introduction

This paper contains a warning for investors, executives, analysts and scientists about the sustainability of the biotechnology industry. The study upon which the paper is based examines the impact of market forces on the biotechnology industry and argues that the short-term focus of market driven policies and practices impacts on the sustainability of firms operating in the industry. The biotechnology industry is a science led industry with R&D cycles and product lead times of 20–30 years [1]. When this is juxtaposed against the shorter-term perspective of venture capitalists, financiers, managers, government, industry analysts and other investors, problems of a mismatch are created between industry viability and stakeholder expectations. The authors argue that these stakeholder expectations and definitions of success in the biotechnology sector utilise perspectives that emanate from out side the sector, particularly from the previous boom industry, IT. We argue for a greater alignment within market expectations and the planning and investment horizons suited to the biotechnology industry and its firms.

A clear elaboration of this short-term approach as applied to high-technology industries can be viewed in the sudden and rapid rise of the concept of the new economy that has encapsulated both popular and academic business literature [2]. For many investors, references to the new economy created associations between high-technology industries, firms and stocks with expected high rates of market returns. Little consideration was given to the structural characteristics of the industries that drive the wealth creation process, R&D life cycles and marketable outcomes. The resultant new economy hype associated with high-technology generated a new arena of trendy industries i.e. biotechnology, information and communication technologies, sustainability and green technologies, software and other digital systems [3–7]. The underlying theme in this contemporary literature argues that the 'new economy' and its associated industries is based on an economy where the central sources of productive activity are moving from primary and secondary sectors, towards the services and information sectors of the economy [8]. For these commentators, these companies and industries represented the 'new' skills, investment focus and industrial landscape of the future [8,9].

To many observers, the biotechnology industry fits this new economy profile because of its reliance on physical capital, the use of a highly skilled workforce, its science based core and knowledge as a key competitive capability. We argue that linking these high-technology industries to faddish terms such as the new economy is simple at best and highly misleading and damaging to the creation of sustainable industries and economies at worse. We take the biotechnology sector as a case of a sector that requires the reconsideration of expectations.

Through the application of bibliometric data (using both refereed and non-refereed papers), matched with the long term tracking of the NASDAQ Biotechnology Index, the authors provide a clear indication that the short-term investment thinking is leading an industry that is characterised by long R&D cycles. There is an incompatibility

between the shorter-term investment considerations and the long-term scientific developments that the biotechnology industry is attempting to achieve.

## 2 Biotech industry characteristics

Biotechnology has been recognised world wide as a critical sector to national economies [10]. This investment is crucial to the growth and continuity of the industry, as it is an industry characterised by high cost research and development (R&D), limited commercialisation, and rapid change brought about by constant technological developments and scientific advances.

Market-driven boom–bust cycles evident in other high-tech industries also impact on the biotechnology industry; this disregards the obvious tangibility of the product and the depth of the science backing the industry. Two key characteristics can be used to differentiate the different structural characteristics of the biotechnology industry from other high-tech sectors [11]. These two characteristics are: diffusion of innovations and practices and innovation speed.

## 3 Diffusion of innovations and practices

In many industries, technological developments have increased the diffusion of innovations through improved speed and quality of communication, improving market knowledge of both producers and consumers. Internet, e-mail, access to generic technologies (such as commercial off the shelf technology), have all contributed to the speed at which ideas and products spread. However, the main issue is that for biotechnology, due to high capital costs, technology diffusion will be slow without significant levels of investment. This investment tends to come either from Big Pharma or from public and private investors. As opposed to the IT industry where $2–3 million would be required to get software designed, developed and on to the market within a 6–12-month period; in biotechnology, "a typical drug takes 15 years and $500 million to bring to market" [12].

Furthermore, there is a very distinct difference between heroic/basic/blue sky research which is largely undertaken by public organisations such as universities, government agencies and research institutes, and incremental/applied R&D that private sector firms are more likely to be involved in. Big Pharma are increasingly outsourcing their R&D (an increase from 5% to 25% in the last decade [13]) as they merge and seek to concentrate on market sales. Such a trend indicates that these companies recognise the long-term viability and importance of the research and diffusion of innovation process to new product development. A point which is missed by short term, market driven time horizons which are at odds with these industry structural characteristics.

Product diffusion is a problematic area for many biotech firms. Realistically, most are research-oriented firms surviving on their inventiveness and innovativeness, based upon the quality of the science and originality of the research, usually indicated by the extent and value of intellectual property such as patents. The manufacturing environment is not a facet of business most are adept in. In fact, many small biotech firms, the type seeking to list or recently listed, choose to stick to the R&D and license their IP to other manufacturers for production. This allows the biotech firm to focus on their core business

R&D, particularly as such licensing deals can be lucrative. By way of example, Genetic Technologies (GTG), a small Biotech company has recently licensed its non-coding DNA patents to Myriad Genetics. An initial payment of $1.85 million was paid to GTG permitting it to expand its research agenda [14].

For the larger and even many medium biotech firms, this is not really an option. Not only does the firm invent products, it must also bring them to market to ensure the cash flow that will fund the 'innovation stream'. The dilemma is firstly for firms to work out their strategic position and where their core business lies along the value chain. If they are more than an R&D firm, then they must manage product development and product diffusion effectively. This therefore requires significant capital resourcing and understanding by investors of the long time horizons involved in the industry. If expectations are for rapid growth and return on investment, as in IT, then these expectations will not be met, funding will dry up, further slowing the diffusion of innovation process.

## 4 Innovation speed

Biotechnology companies face a far more extended R&D pipeline, in general, than many other high-tech industries [1]. While the product life cycle may extend beyond that of other industries, the entire R&D cycle can reach 20–30 years [11]. Given that patents are granted relatively early on in this cycle, companies must then achieve a dramatic return on investment over a time span as short as five years before competitor products can be legally launched on the market. Competitors, to access the codified knowledge required to replicate the product, are in the meantime using patent documents and publications in scientific journals such as *Nature*, *Lancet*, and various other medical journals, to have their products market ready for patent expiry.

While product life cycles are short (though not necessarily reducing), there are also limitations to the ability to reduce R&D cycles in biotech companies. Innovation speed [15], a fundamental competitive factor in many industries is a significant challenge to Biotech companies. Innovation speed is inextricably linked to diffusion. Based on the R&D cycle, innovation speed refers to the length of time it takes for a product to move from idea to commercialisation [15].

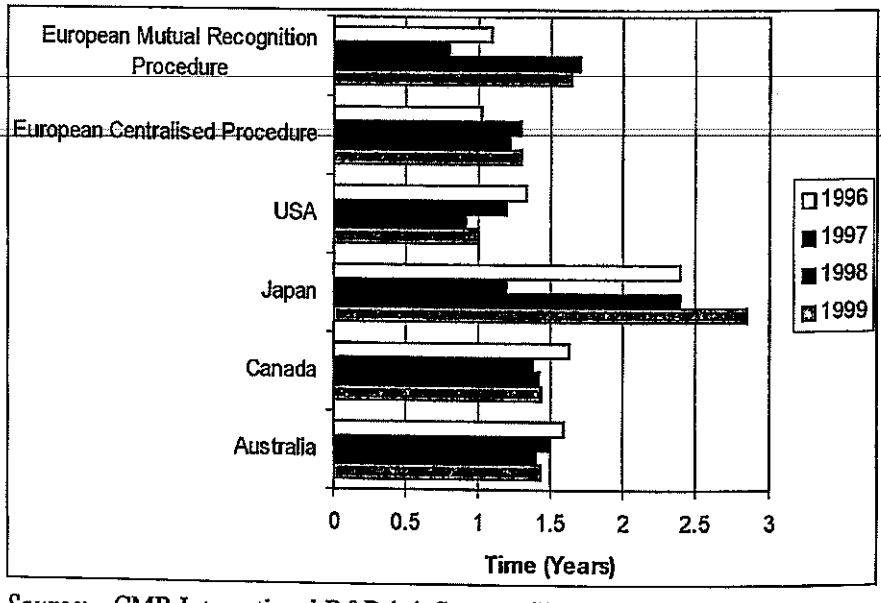
The steps which must be followed in this R&D pipeline include:

- Discovery Research
- Preclinical Testing (Lab and animal testing)
- Phase I (20–30 healthy volunteers testing for safety and dosage)
- Phase II (100–300 patient volunteers used to check for efficacy and side-effects)
- Phase III (1000–5000 patient volunteers to monitor reactions to long-term drug exposure)
- FDA Review and Approval Post-market Testing.

Typical of the length of the Biotech R&D cycle is the approval times of the major drug approval bodies international, such as the FDA in the USA, the TGA in Australia, and EUDC in Europe. Figure 1 below indicates the average approval times for New

Molecular Entities (NMEs), the outcome of an important area of effort in Biotech. While it varies dramatically between countries, approval times are not less than 12 months. Further, this is only one step in the entire R&D process for most biotech products.

**Figure 1** Median new molecular entities (NME) approval times (1996–1999)




*Source*: CMR International R&D briefing, profile of performance.

In biotechnology, the set approval process, and the requirement for the trial phases prior to the approval process all serve to limit the extent to which Biotech companies have control over the R&D cycle and are able to reduce it. It is only through reducing the R&D cycle, thereby enhancing innovation speed, that more time is provided for returns on investment before patent expiry.

It is critical for the long-term viability of the biotechnology industry to study the impact the market has on this science based industry. One way to achieve this is to compare market trends with the popular and scholarly literature on the industry. The assumption is that scholarly academic work will lead popular thought and show trends that vary from those closer to the market, namely non-academic publications, as well as vary from the market trends themselves. This is the focus of the study upon which this paper is based. However, the proposition put forward by the authors is that the market is leading the scholarly academic publication process in the business and management realm. Therefore, the market will be pre-eminent in its influence on the industry.

## 5 Methodology

The sustainability of an industry should be indicated by the level of innovation occurring in the industry, demonstrating the likely product stream that will maintain the growth path of the industry. In biotechnology, this product stream is indicated by both scientific publications and its commercial parallel intellectual property, most commonly indicated by patents. However, patents can be considered a defensive strategy for companies, research institutions and researchers [16], with the express purpose of limiting competition in a market so that the patent holders can achieve reasonable return on investment, before competition is permitted in that market. Publications about scientific

discoveries, as this is a discovery-based industry, based upon substantial research and development, provide a pure vision of the state of play of the science and the future direction of the products developed for the industry.

However, there is another body of literary publications that are not of a physical scientific nature. These are the publications about biotechnology from a management, economic, financial, strategic, sociological and even anthropological perspective. While no less relevant, these publications, and their studies, are one step removed from the science. They tell the story of the state of play of the wider industry largely from a phenomenological stance.

To extricate the substance of the term biotechnology, a series of research tasks was undertaken. First, a survey of the major business related online literature databases (Ebscohost, Expanded Academic ASAP and Proquest) of the term 'biotechnology' was performed.

A frequency count of papers with the selected terms in their titles was undertaken using the three major and most commonly used business databases. The count covers the period 1984 to the present (which allows for a longer-term view of the market and publication trends). Academic, industry and popular journals were included in the analysis in this first inclusive sweep of the literature. Papers involving book reviews were not included in the analysis. The results of this survey are presented in graphical form in the next section.

Then a comparison is undertaken between the frequency counts of the major terms of interest in this study and the state of play of the NASDAQ, as indicated by the NASDAQ Composite Index. This two-part analysis looks at comparing:

- the frequency count for biotechnology is compared against the NASDAQ Composite Index to gauge whether there is a visual association between the progress of the NASDAQ and the popularity in use of the term biotechnology in both academic in popular press
- the frequency count for biotechnology in the academic literature (refereed publications) and the state of play of the NASDAQ.

Refereed publications were selected for comparison in the second task above, as it would be expected that while the academic literature is slower to pick up on a new development as practice is metamorphosed to theory, the theoretical and critical analysis of concepts such biotechnology are more comprehensively analysed over an extended period of time. Therefore, the patterns of citation should not show the same diffusion shape to that of the phenomenon it is analysing. In undertaking the three research tasks indicated above, a thorough exploratory analysis of the sustainability of the concept of biotechnology is achieved.

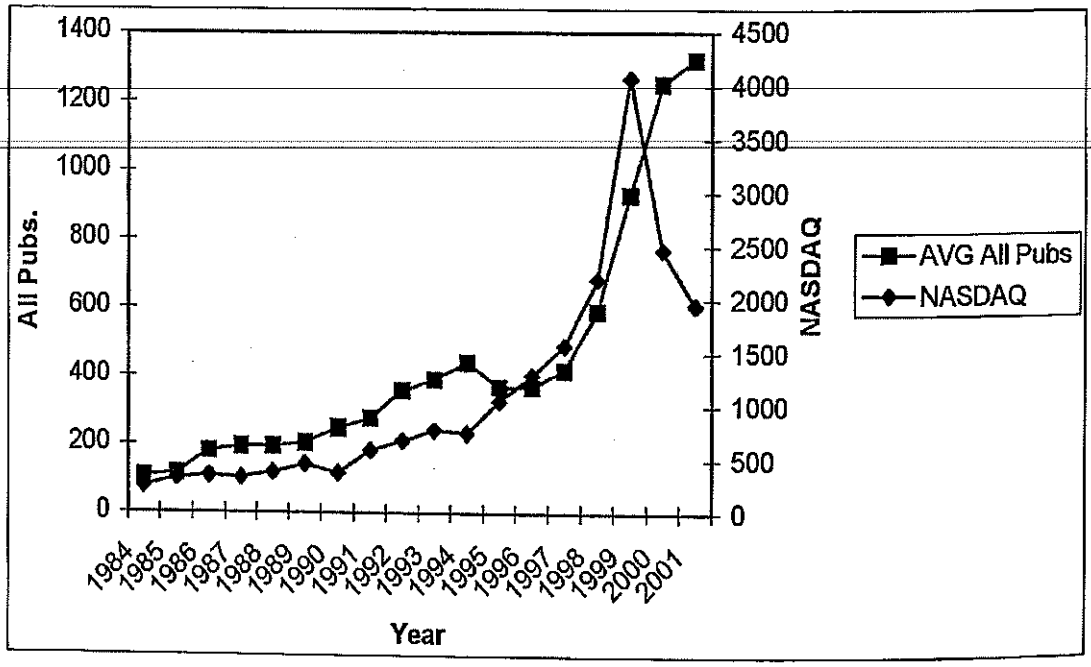
## 6 Results

### *6.1 NASDAQ and citation comparison*

It is obvious from the three databases used that it is the business of biotechnology, rather than the science, which is of central importance in this paper. Figure 2 shows that from 1984 to 2001, all publications followed the same trendlines as a significant major

indicator of the market popularity of biotechnology – the NASDAQ. This indicates a lag time for publications. We would anticipate that as the NASDAQ indicator for biotechnology dropped, the lag in publications will also reflect the same change.

**Figure 2** Average of all publications on biotechnology against the NASDAQ

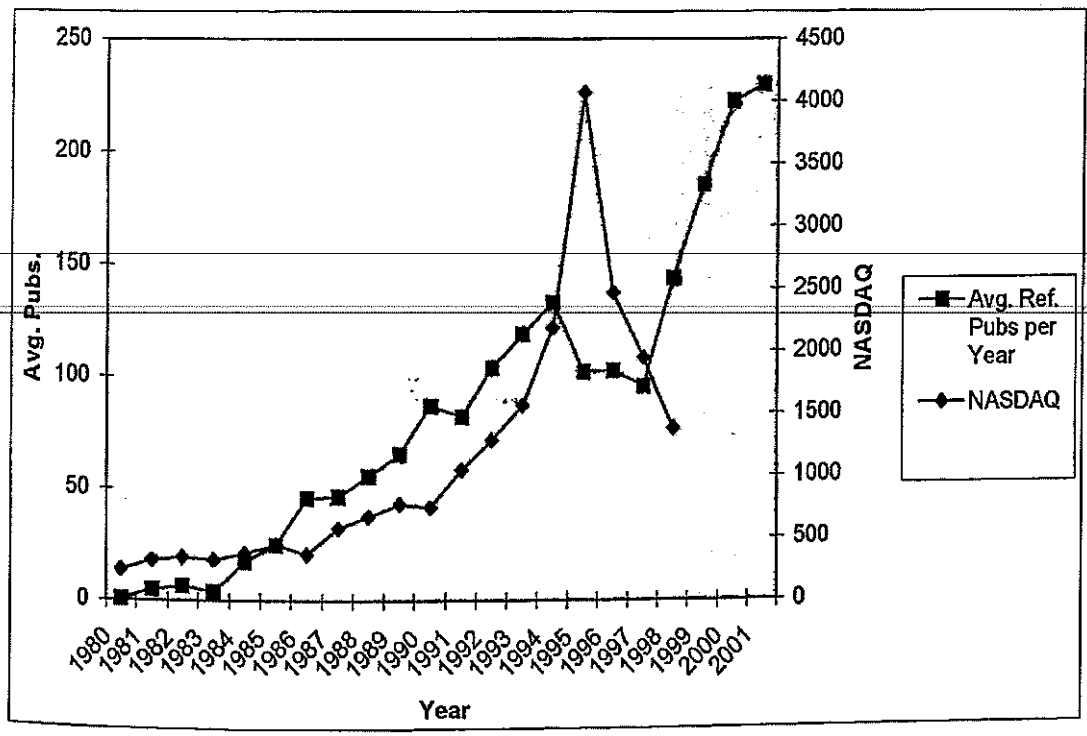



*Source*: ABI Inform, Expanded Academic ASAP, Business Source Premier, NASDAQ.com.

It is clearly evident in Figure 2 that catastrophic events have occurred in the NASDAQ financial market. The high-tech boom has come and gone and the fallout continues with collapses such as WorldCom and dramatic declines in companies such as Yahoo, Netscape and Lucent Technologies. Paralleling this dramatic boom–bust cycle is the citation rate for biotechnology. Interestingly, the results show that citations in both academic and popular press for biotechnology have mirrored and lagged this cycle. It would seem then that the publication process is taking its lead from the activity of the NASDAQ. The significant lag between the 1999–2000 drop in the NASDAQ, and drop in publications, providing evidence of practice leading theory, further highlights the significance of this lag.

Figure 3 also presents the average frequency counts of the various terms from the three databases. The frequencies were averaged in an attempt to take into account similarities in the journal catalogues between the databases. However, Figure 3 provides a more defined analysis as it only considers academic citations for biotechnology. Despite this qualification in favour of the academic literature, a similar pattern is repeated. These results prompt significant questions over the sustainability of management concepts and the leadership role of academics in guiding and evaluating important developments in economies.

**Figure 3** Average of refereed papers against the NASDAQ



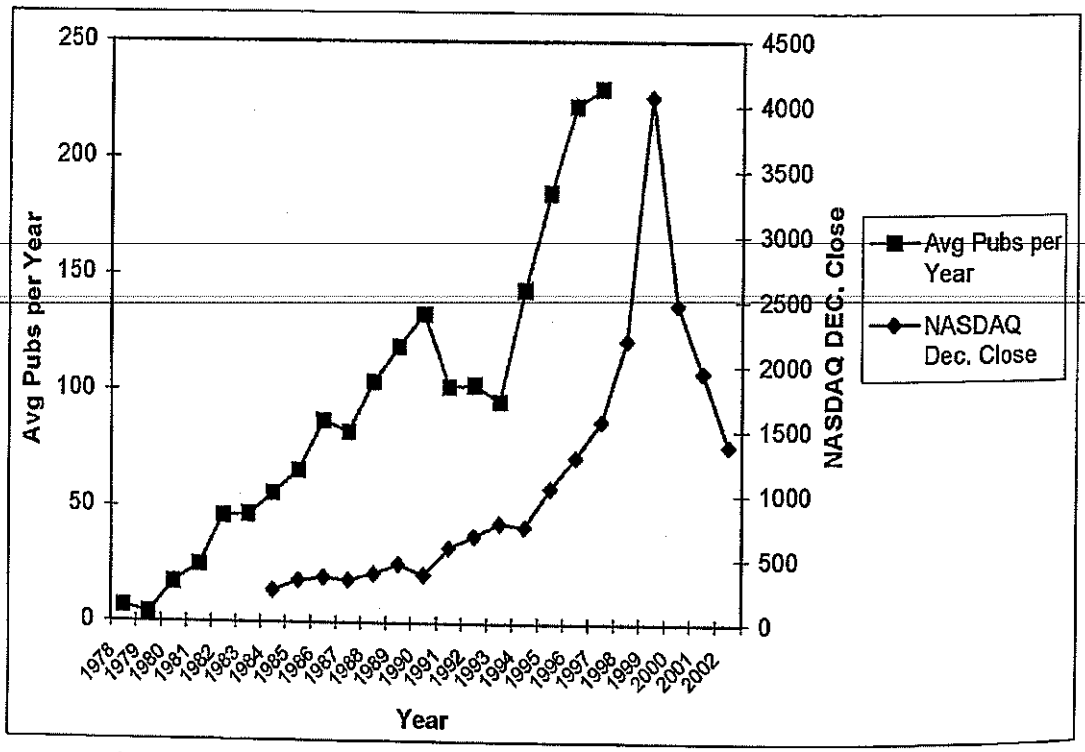

*Source*: ABI Inform, Expanded Academic ASAP, Business Source Premier, NASDAQ.com.

In the period from 1996 to 1999, the NASDAQ Index displayed exponential growth, that is, it was increasing at an increasing rate. Diffusion theories (such as Gupta and Bass models) inform us that rapid rises along the diffusion curve will be followed by rapid falls. Such steep peaks and troughs do not lead to sustainable outcomes for an industry.

As the academic papers mirror the rise and fall of the NASDAQ, this raises questions as to the ability of the academic community to evaluate and test the assumptions upon which their supposedly empirical literature is based. This may well be indicative of the rapidity of change occurring in industrial markets, providing scholars with insufficient warning of the industrial developments to permit the usual checks of rigor and theoretical soundness.

In Figure 4, we have shifted the trend line of the refereed publications forward two years to remove the lag time of the publication process, which would tend to average two years. By doing this, we seek to remove the disadvantage for social science researchers getting their ideas to 'market' as quickly as possible in reputable form. The shift forward two years in the trend line takes account of the lead times in publishing scholarly journal papers. If this lead-time is accounted for, then the relative advancement of the thinking, the idea generation that leads to the research that leads to the published papers should become more apparent. It would be expected then that the scholarly works would display their predictiveness by tailing off prior to the technology bubble bursting in 2001.

**Figure 4** Average of refereed papers and NASDAQ with the lead times accounted for




*Source*: ABI Inform, Expanded Academic ASAP, Business Source Premier, NASDAQ.com.

There does appear to be a slow down just prior to the technology crash, though this would need to be tracked into the future for a true picture to be gained of the foresight shown by academics. Unfortunately the world beyond academia was not warned of any shift in thinking for two years hence, given the publishing lead times. The publishing process appears to dramatically mitigate the impact of the academic as a 'bell-weather' for industry.

## 7 Discussion and conclusion

There are several important lessons to be drawn from this analysis for high technology industries. We think that the first to note is that the biotechnology industry is shifting from an emerging industry to a more mature industry. There is evidence of a shift along the value chain for the industry, from an emphasis on discovery research to development, manufacture and marketing. This was identified by Mark Levin CEO of Millennium Pharmaceuticals [12] in his observation that

> "value has started to migrate downstream, towards the more mechanical tasks of identifying, testing, and manufacturing molecules that will affect the proteins produced by genes, and which become the pills and serums we sell."

This shift in the creation of value along the value chain will continue to occur as more companies move through their trial phases and approval processes towards the market. This commercialisation push is also supported by the number of drug approvals indicated by the FDA's Center for Drug Evaluation and Research [17].

It would be dangerous to withdraw investment funding at this stage where, more than ever before, it can be argued that the industry is on the brink of making a commercial return for investors. However, the short-term demand on returns made by market driven polices and practices prove to be disruptive rather than enhancing the long-term sustainability of the industry. While market capitalisation is important to this industry, so too is its scientific base. Market driven cycles can only serve to exacerbate a split between biotechnology and its scientific base – where capability activities should be seeking to build this.

Further, financial benchmarks are critically important as a basis for judging investment decisions for listed companies. Yet, how can we have a price to earnings ratio for a company, which has no earnings? Put simply, many of the biotech ventures do not have sales revenues. Down the track when their licences start producing progress payments, there will be something to consider. Also, where the venture undertakes such commercial tasks as contract research, there will be revenue to consider.

Much of the empirical evidence on generating sustainable competitive advantages for firms, industries and national economies is not simply achieved by the creation and substitution of new technologies (such as the internet), firms or industries for sustainable strategies [18] or the development of industry and firm capabilities [19]. Rather, anecdotal evidence suggests that management fads make it difficult to discern when and how companies engage with new practices [20]. Biotechnology has gained interest in both the refereed and the popular literature in recent years, fuelled by its inclusion in the tech boom [21]. Yet a priori reasoning and the preceding literature would suggest that biotechnology should not be automatically lumped with the other recognised high-technology industry – IT. In fact, this association may well be unfortunate for the biotechnology industry, particularly where investors apply the same investment criteria to this industry as they have in IT. Most IT products require R&D cycles which are quite short when compared with products such as pharmaceuticals, medical equipment, computer hardware and even complex software such as SAP and Peoplesoft [22].

Finally, a focus on fads masks continuities in industrial and firm development and can lead to poor investment decisions. Take, for example, a common interpretation of the 'new economy' that associated with the differentiation from an earlier industrial period. As such new economy firms are presented as having distinctive attributes, capabilities and qualities that make them more suitable to the conditions of turbulence and discontinuity of the 'new economy era' [23]. However, this emphasis on 'newness' and discontinuity masks the dynamics of industry creation and firm capabilities associated with knowledge and innovation [19]. It is a reality that new industries emerge from established industries, they do not simply spontaneously generate. In this way, it is harmful to all industry stakeholders to artificially differentiate a high technology industry.

There is certainly scope for further research to carry this analysis forward. There are limits to the current paper due to the reliance on a bibliometric technique alone. The next step in the research is to undertake a more direct comparison between market trends and scientific publications, as well as the business-oriented publications. This however is an onerous task, as the term Biotechnology is largely an artificial construct that encompasses a large array of scientific pursuits from proteomics, to bioinformatics, to agricultural biotechnology and bioremediation, to cell therapies and even nanotechnology. Counts will need to be conducted in all areas associated with biotechnology.

The analysis lends itself to more extensive quantitative analysis using hypothetico-deductive techniques, testing for relationship and causality as well as trend

analysis. There are substantial lessons to be learned from this apparent experience. It is certainly not the first fad that has emerged, as the quality management fraternity can attest to. It certainly will not be the last. Yet, if we can go some way toward undertaking a test of the validity of emerging concepts in both the academic and popular literatures, then we can save our industrial counterparts some grief (while saving substantial amounts on management consulting fees).

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